IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

UNITED STATES OF AMERICA, Plaintiff, v. BEN VENUE LABORATORIES, INC., a corporation, and GEORGE P. DOYLE III, KIMBERLY A. KELLERMANN, and DOUGLAS A. RICH, individuals, Defendants.	CIVIL NO. 1:13 CV 154

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Ben Venue Laboratories, Inc. ("BVL"), located in Bedford, Ohio, and George P. Doyle III (who assumed his position as BVL's President and Chief Executive Officer on August 29, 2011), Kimberly A. Kellermann (who assumed her position as BVL's Vice President of Operations on October 18, 2011), and Douglas A. Rich (who assumed his position as BVL's Vice President of Quality Operations on July 1, 2012) (collectively, with BVL, "Defendants"), and Defendants, having appeared and consented to the entry of this Decree without contest, without admitting or denying the allegations in the Complaint, and before any

testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "Act").

3. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drugs, as defined by 21 U.S.C. § 321(g), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of the current good manufacturing practice ("CGMP") requirements for drugs, *see* 21 C.F.R. pts. 210 and 211.

4. The Complaint alleges that Defendants violated the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drugs after the shipment of one or more of their components in interstate commerce.

5. For purposes of this Decree, the following definitions shall apply:

A. "BVL facilities" shall refer to all Ben Venue Laboratories, Inc. facilities located at 300 Northfield Road, Bedford, Ohio 44146 and/or any new facilities built or redesigned to manufacture drugs in Bedford, Ohio;

B. "Drug(s)" shall have the meaning given to the term in 21 U.S.C. § 321(g), and shall include finished drug products, in-process materials, bulk drug substances, and components thereof; and

C. "Days" shall refer to calendar days unless otherwise stated.

INJUNCTIVE PROVISIONS

6. Except as provided in paragraph 9 below, Defendants and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any drugs, or causing any of the foregoing, at and/or from the BVL facilities, unless and until:

A. Within ten (10) days after the entry of this Decree, Defendants retain, at BVL's expense, an independent person or persons (the "expert") to inspect the BVL facilities in the manner described below. The expert shall be qualified by background, training, education, and experience to conduct such inspection and shall be without personal or financial ties -- other than a consulting agreement with Defendants -- to Defendants or their immediate families. Defendants shall notify FDA in writing of the identity and qualifications of the expert within ten (10) days of retaining such expert. In the event Defendants replace such expert, Defendants shall notify FDA in writing of any such replacement within ten (10) business days after such replacement. Any replacement expert shall be qualified as described herein.

B. The expert conducts a comprehensive inspection of the BVL facilities to determine whether the methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute drugs comply with the Act, its implementing regulations, and this Decree. This inspection shall be completed no later than one hundred fifty (150) days after entry of this Decree. In conducting this inspection, the expert shall review all CGMP deviations at the BVL facilities brought to Defendants' attention in writing since June 2007 by FDA (including, but not limited to, all Forms FDA-483 issued to

BVL), the expert, any former CGMP consultants for BVL, and any foreign regulatory authorities. The expert's inspection shall include, at a minimum, an evaluation as to whether:

1. Defendants have made comprehensive facility and equipment design enhancements and/or replacements;

2. Defendants have established a comprehensive, written quality assurance and quality control program ("QA/QC program") that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. At a minimum, the expert shall determine whether the QA/QC program:

a. Operates in coordination with, and under appropriate oversight of, BVL's QA/QC management;

b. Addresses compliance monitoring and trend analyses necessary to effectively manage CGMP compliance, records management systems, and internal audit procedures;

c. Includes written standard operating procedures ("SOPs") to ensure that Defendants: (i) thoroughly investigate and document in a timely manner any unexplained discrepancy and/or the failure of a batch of drug or any of its components to meet any of the drug's or component's specifications, including the extension of such investigation to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy; and

(ii) takes required and timely corrective actions for all products that fail to meet specifications;

d. Includes written SOPs to ensure that Defendants thoroughly investigate and document in a timely manner any drug complaint, return, or adverse event, and any associated trends in these product quality deviations and/or problems, and take any needed corrective actions in a timely manner;

e. Includes written SOPs specifying the responsibilities and procedures applicable to QA and QC personnel and establishes procedures to ensure that such written SOPs are followed;

f. Ensures that BVL's Quality Control Unit, as defined by 21 C.F.R. § 210.3(b)(15), is adequately staffed and its personnel are adequately trained to evaluate CGMP compliance on an ongoing basis to prevent and correct future deviations from CGMP;

g. Includes written SOPs to ensure that BVL's QA/QC management: (i) is promptly notified of deviations and/or problems that could affect the safety, identity, strength, quality, and purity of drug; and (ii) participates in and/or monitors the implementation and verification of corrective actions to prevent future occurrences of such

deviations and/or problems, and that there are procedures to ensure that such written SOPs are continuously followed;

h. Includes written SOPs for the change control system to ensure that Defendants adequately qualify equipment and validate processes when changes are implemented that necessitate such activities. The SOPs shall, at a minimum, require Defendants to document: (i) how the qualification or validation study was conducted, including the test parameters, product characteristics, production equipment, and clear decision points for what constituted acceptable test results; (ii) whether the protocol for the equipment qualification or process validation study was adhered to during execution of the study and, if not, any deviations that occurred and the effect(s) the deviations had on the study's results; and (iii) Defendants' review of the qualification or validation study results; and

i. Includes procedures to ensure that SOPs are periodically re-evaluated so that they remain in continuous compliance with applicable laws and regulations and reflect Defendants' current practices;

3. Defendants' written production and process controls are adequate to ensure compliance with the Act, its implementing regulations, and this Decree. The expert shall, at a minimum, determine whether these production and process

controls:

a. Include written SOPs to evaluate, implement, and control changes to any and all systems, processes, equipment, and tests, including, but not limited to, sterilization processes, lyophilization processes, container and closure cleaning and preparation processes, critical in-process specifications and controls, and release tests and criteria;

b. Adequately ensure that production and process control procedures and protocols will be continuously followed; that production and process control functions are accurately and completely documented at the time of performance; that deviations from procedures, protocols, and established production and process controls are documented and investigated; and that any failure to meet established acceptance criteria (as defined in 21 C.F.R. § 210.3(20)) or process specifications is thoroughly and promptly investigated and documented; and

c. Include a system for reporting to the appropriate QA/QC unit instances in which: production and process control procedures and protocols are not followed; deviations from procedures, protocols, and established production and process controls occur; and/or there are failures to meet established criteria or process specifications;

4. Defendants have implemented a scientifically sound and appropriate system of laboratory controls that, at a

minimum, includes specifications, standards, sampling plans, and test procedures necessary to ensure that components, drug product containers, closures (including container closure integrity), labeling, and drugs are in compliance with the Act, its implementing regulations, and this Decree. As part of this assessment, the expert shall determine whether Defendants' laboratory controls system adequately provides for:

a. Investigations and appropriate scientific analyses of laboratory tests that result in out-of-specification results;

b. Justification for the specific basis for invalidating test results, and plans for retesting products or samples when indicated;

c. Analyses of trends in laboratory failures and maintenance of records showing investigations of such trends; and

d. Statistical quality control criteria and appropriate acceptance and rejection levels;

5. Defendants have implemented an effective buildings and facility control system that describes in sufficient detail cleaning and maintenance schedules, methods, equipment, and materials. The expert shall determine whether the system ensures, at minimum, that: (a) the materials and procedures used to clean and disinfect rooms and equipment in

aseptic processing areas are effective to remove microorganisms, particularly those that are typically isolated in an aseptic processing environment; (b) materials are used in accordance with written procedures; and (c) written procedures are continuously followed and documented;

6. Defendants have implemented an adequate records management system for all records relating to the manufacture, processing, packing, holding, and/or distribution of drugs at and/or from the BVL facilities that are required to be maintained by Defendants' SOPs, the Act, its implementing regulations, and this Decree. The expert shall determine whether the records management system, at a minimum:

a. Ensures documentation of each significant step, recorded completely, accurately, and concurrently with the performance of the step, in the manufacture, processing, packing, holding, and distribution of drugs at and/or from the BVL facilities, including the identity of the person(s) performing such steps and the dates on which each step was taken;

b. Includes procedures to ensure documentation of all investigations and any steps taken to: (i) correct failures of drugs to meet specifications; (ii) prevent future recurrence of failures of drugs to meet specifications; (iii) investigate other batches of drugs that

may have been affected by the same or similar failures; and (iv) evaluate out-of-specification test results;

c. Includes a mechanism to ensure that such procedures are followed; and

d. Includes complete data derived from all tests necessary to ensure compliance with established specifications and standards;

7. Defendants' equipment and facilities used in the manufacture, processing, packing, and holding of drugs are appropriately designed for each of their intended uses and adequately qualified and maintained. The evaluation shall include, but not be limited to, equipment and facilities used to process drug products and drug product containers and closures. The expert shall, at a minimum, determine whether controls exist to ensure that:

a. Equipment is properly calibrated and operating within specifications so as to ensure the consistent safety, identity, strength, quality, or purity of drugs;

b. Equipment and facilities are cleaned, maintained, and, where applicable, perform processes adequately to prevent product contamination, e.g., microorganisms, particulate matter, pyrogens, or other contaminants, that would alter the safety, identity, strength, quality, or purity of drugs beyond the official or other established requirements;

c. Equipment produces drug products with container/closure systems that provide adequate protection against foreseeable external factors that may cause deterioration or contamination of drugs; and

d. Water systems used for rinsing, cleaning, manufacturing, and storage are adequately designed, validated, maintained, and routinely tested for compliance with all applicable specifications;

8. Defendants have procedures in place to ensure that their manufacturing processes, systems, and controls are adequately validated;

9. Defendants' employee training and qualification practices are adequate, including, but not limited to, employee training and qualification in CGMP, aseptic processing, inspection techniques, and procedures for responding to product quality deviations, to ensure that Defendants manufacture drug products in conformance with the CGMP requirements for drugs; and

10. Defendants have implemented a system to ensure the adequate receipt, identification, storage, holding, sampling, testing, and re-evaluation of active pharmaceutical ingredients.

C. Within twenty (20) days after completing the inspection, the expert: (1) prepares a detailed, written report

of the expert's inspection, which addresses, at a minimum, each of the matters described in paragraphs 6.B.1-10 above and whether the deviations at the BVL facilities brought to Defendants' attention in writing since June 2007 by FDA, the expert, any former CGMP consultants for BVL, or any foreign regulatory authority have been corrected; and (2) delivers that report contemporaneously to Defendants and FDA. In preparing this report, the expert may rely on work or actions the expert performed prior to entry of this Decree.

D. 1. Within seventy-five (75) days after receiving the expert's inspection report, Defendants submit a written report to FDA detailing the specific actions Defendants will take to address the expert's observations and to bring Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute drugs at and/or from the BVL facilities into compliance with the Act, its implementing regulations, and this Decree (hereinafter, "the remediation plan"). The remediation plan shall include a schedule for Defendants' review of the validation studies for drugs listed on Attachment A and manufactured by Defendants to ensure that for each: (a) the validation protocol adequately specified how the study was to be conducted, including test parameters, product characteristics, production equipment, and criteria for release of products; (b) the protocol was adhered

to during its execution (and if not, that any deviations that occurred had no negative impact on the study's results); and (c) the results of the study demonstrate that the manufacturing process for the drug is adequately validated.

2. The specific actions in the remediation plan shall be set forth in numbered steps and, where appropriate, the numbered steps may include subordinate lettered steps. The remediation plan shall include a timetable with specific dates for completion of each numbered step and may include, where appropriate, interim dates for completion of subordinate lettered steps.

3. The remediation plan, including its proposed specific actions and timetable, shall be subject to FDA approval, which approval decision will be made within sixty (60) days of submission of the complete remediation plan. Defendants shall ensure the implementation of the numbered steps in the remediation plan in accordance with the timetable approved by FDA.

E. As the actions detailed in the remediation plan are completed, Defendants notify the expert in writing, and such expert shall promptly inspect and verify whether those actions have been completed in a manner that complies with the Act, its implementing regulations, and this Decree, to the expert's satisfaction and in accordance with the remediation plan

approved by FDA. If the expert determines that an action has not been completed to the expert's satisfaction, the expert shall promptly notify Defendants in writing. Beginning thirty (30) days after FDA's approval of the remediation plan, and quarterly thereafter, the expert shall submit to FDA a table that succinctly summarizes the expert's findings as to whether the actions have been completed to the expert's satisfaction and in accordance with the remediation plan approved by FDA. FDA may, in its discretion and without prior notice, periodically inspect the BVL facilities and undertake such additional examinations, reviews, and analyses to verify whether the actions reported to have been completed have in fact been completed in a satisfactory manner. In the event that FDA determines that an action that has been reported to be completed is inadequate, FDA will notify Defendants in writing, and Defendants shall take appropriate action in accordance with a timetable that is subject to approval by FDA.

F. When the expert determines that all of the actions identified in the remediation plan approved by FDA have been completed to the expert's satisfaction, the expert promptly submits contemporaneously to Defendants and FDA a written certification that all of the actions have been completed and that, based on the inspection conducted under paragraph 6.B. and on the satisfactory completion of the actions in the remediation

plan identified under paragraph 6.D, Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute drugs at and/or from the BVL facilities are, and if properly maintained and implemented by Defendants, will continuously remain in conformity with the Act, its implementing regulations, and this Decree.

G. Within forty-five (45) days after receipt of the expert's certification, FDA may, in its discretion and without prior notice, begin an inspection of the BVL facilities and undertake such additional examinations, reviews, and analyses as FDA deems appropriate to determine whether Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute drugs at and/or from the BVL facilities are in conformity with the Act, its implementing regulations, and this Decree.

1. If FDA determines that Defendants are not operating in conformity with the Act, its implementing regulations, and this Decree, FDA will notify Defendants of the deficiencies it observed and take any other action FDA deems appropriate (e.g., issuing an order pursuant to paragraph 15).

2. Within thirty (30) days after receiving this notification from FDA, Defendants shall submit to FDA a plan describing the actions Defendants propose to take and a timetable for correcting the deficiencies, which plan and

timetable shall be subject to FDA approval. Defendants shall promptly correct all deficiencies noted by FDA in accordance with the FDA-approved timetable, and cause the expert to re-inspect the conditions relevant to the deficiencies noted by FDA and to either (i) certify that the deficiencies have been corrected to ensure that Defendants' methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute drugs at and/or from the BVL facilities are in conformity with the Act, its implementing regulations, and this Decree, or (ii) notify Defendants and FDA in writing that one or more deficiencies remain uncorrected. If one or more deficiencies have not been corrected, Defendants shall correct the deficiencies to the expert's satisfaction, at which point the expert shall issue a certification of compliance to Defendants and FDA.

3. Within forty-five (45) days after receipt of the expert's certification under subparagraph 2, FDA may, in its discretion and without prior notice, begin a re-inspection of the BVL facilities as it deems necessary.

H. FDA determines that the manufacturing, processing, packing, holding, and distribution of drugs at and/or from the BVL facilities appear to be in conformity with the Act, its implementing regulations, and this Decree, and notifies Defendants in writing, as described below in

subparagraphs (1) and (2) below.

1. If FDA conducts an inspection or re-inspection pursuant to paragraph 6.G and finds that the manufacturing, processing, packing, holding, and distribution of drugs at and/or from the BVL facilities appear to be in conformity with the Act, its implementing regulations, and this Decree, this notice will be issued within sixty (60) days after completion of the latter inspection.

2. If FDA elects not to conduct an inspection or reinspection pursuant to paragraph 6.G, this notice will be issued within forty-five (45) days after receipt of the expert's certification under paragraph 6.F.

7. A. Before issuing a certification that all actions specified in the remediation plan have been completed under paragraph 6.F, the expert may issue a written certification with respect to one or more BVL facilities, individual production line(s) therein, or specific systems or operations at the BVL facilities. The expert shall certify that the methods, facilities, processes, and controls used by Defendants -- including those performed by a third party -- to manufacture, process, pack, hold, and distribute drugs at and/or from the facility, line, or system at the BVL facilities that is the subject of the certification comply with the Act, its implementing regulations, and this Decree.

B. FDA's review of this certification will progress in the same manner and be subject to the same timelines as set forth in paragraph 6.G.

C. If FDA determines that the methods, facilities, processes, and controls used to manufacture, process, pack, hold, and distribute particular drugs at and/or from the BVL facility or facilities, line(s), or system(s) that is the subject of the certification comply with the Act, its implementing regulations, and this Decree, FDA will notify Defendants in writing, as described below in subparagraphs (1) and (2) below.

1. If FDA conducts an inspection or re-inspection pursuant to paragraph 6.G (incorporated by reference in paragraph 7.B), this notice will be issued within sixty (60) days after completion of the latter inspection.

2. If FDA elects not to conduct an inspection or re-inspection pursuant to paragraph 6.G (incorporated by reference in paragraph 7.B), this notice will be issued within forty-five (45) days after receipt of the expert's certification under paragraph 7.A.

D. Nothing in paragraph 7 shall excuse Defendants from their obligations under paragraph 6 to come into compliance with the Act, its implementing regulations, and this Decree.

8. After FDA issues a notice to Defendants pursuant to paragraphs 6.H or 7.C., Defendants shall not distribute a drug not listed on Attachment A until Defendants have completed adequate validation testing for that drug to ensure that: (a) the validation protocol adequately specified how the study was to be conducted, including test parameters, product characteristics, production equipment, and criteria for release of products; (b) the protocol was adhered to during its execution (and if not, that any deviations that occurred had no negative impact on the study's results); and (c) the results of the study demonstrate that the manufacturing process for the drug is adequately validated.

EXCLUSIONS

9. Notwithstanding the injunctive provisions in paragraph 6 of this Decree, Defendants may conduct the following activities at the BVL facilities:

A. Manufacturing, processing, packing, labeling, holding, and distributing the drugs listed on Attachment A;

B. Subject to the conditions in paragraph 7, manufacturing, processing, packing, labeling, holding, and distributing drugs at and/or from the BVL facilities, lines, systems, or operations covered by a notification issued by FDA under paragraph 7.C;

C. Manufacturing, processing, packing, testing,

labeling, holding, and distributing drugs solely for the purpose of performing equipment qualification, validating drug manufacturing processes, or conducting method validation or stability studies. Defendants shall maintain in a separate file at the BVL facilities a written log of all lot numbers of drugs manufactured under this provision, and shall promptly make such log available to FDA upon request. Such drugs shall not be commercially distributed without FDA's prior consent;

D. Holding, repackaging, and distributing any drugs manufactured, processed, packed, labeled, held, or distributed at or by third parties, so long as neither Defendants nor third parties perform any manufacturing, processing, or labeling functions (other than labeling necessary for repackaging) with respect to the drugs at the BVL facilities, and BVL's sole responsibility is that of a repackager and distributor;

E. Manufacturing, processing, packing and/or holding drugs for the sole purpose of preparing or supporting a new drug application (NDA) or an abbreviated new drug application (ANDA) (including drug product for the conduct of clinical or non-clinical laboratory studies or other research and testing), or supplement to either but such drugs may not be distributed without prior written authorization from FDA. FDA will respond within ninety (90) days to a request from Defendants to distribute drugs pursuant to this paragraph;

F. Receiving, holding, testing, and distributing active pharmaceutical ingredients. Defendants shall provide a copy of this Decree to each purchaser of active pharmaceutical ingredients; and

G. Manufacturing, processing, packing, holding, and/or distributing drugs in accordance with a written request by Defendants to FDA, provided that: (i) Defendants have submitted to FDA all documentation and justification for such request that FDA deems necessary; and (ii) FDA has authorized Defendants in writing to perform such activity with respect to such drugs.

ADDITIONAL REQUIREMENTS

10. A. For each batch of drugs referred to in paragraph 9.A, the manufacture of which has begun after the date of entry of this Decree and before issuance of the notice under paragraph 6.H with respect to the BVL facilities, Defendants' expert shall, prior to the distribution of each batch, review all in-process, bulk, and finished batch production records for that batch and either:

1. Certify that, based upon the expert's review, no deviations occurred during the manufacture of the batch that, in the expert's professional opinion, would, during its labeled expiration period, adversely affect the safety, identity, strength, quality, or purity of the batch or cause the

batch to fail to meet any and all applicable approved specifications established in its application; or

2. If the expert is unable to make the certification described in subparagraph 1 above, deliver a written report to Defendants, explaining the expert's reasons for not so certifying the batch, which report shall include:

a. A list of all deviations from written procedures found in the batch production records; an assessment as to whether an adequate investigation (including the identification of root causes) was conducted with respect to the deviations and whether adequate corrective actions have been taken; an evaluation as to whether such investigations were conducted in a timely manner;

b. An assessment as to whether any deviations might have adversely affected the safety, identity, strength, quality, and purity of the batch;

c. A list of any deviations and/or problems that BVL's QA/QC program personnel failed to address during their review of the batch production records for release of the batch; and

d. A determination whether the batch must be destroyed or could be rehabilitated and possibly certified.

B. Before the expert's written certification under paragraph 10.A.1 above has been issued for a batch, Defendants

shall not release the batch except that Defendants may ship the batch to a third party for further processing or holding, but in so doing, Defendants shall maintain the batch under quarantine and shall not release the batch until the expert's written certification is issued.

C. Defendants shall, on a quarterly basis following the date after entry of this Decree, submit to FDA a summary of the results of the expert's reports under paragraph 10.A.2, specifically indicating, for each quarterly period, the number of batches reviewed, the number of batches certified, the number of batches not certified and, for the non-certified batches, the expert's reasons for the non-certification and recommendations for disposition.

D. Defendants shall maintain copies of all expert certifications and reports submitted pursuant to paragraph 10.A in a separate file at the BVL facilities and copies shall be made immediately available to FDA upon request.

11. FDA shall have the sole and unreviewable discretion to add or delete any drugs on the list of drugs on Attachment A referred to in paragraph 9.A, either on its own initiative or after consideration of a written request from Defendants. The decision to delete a drug from the list of drugs on Attachment A will be made by the Director of the Center for Drug Evaluation and Research after considering whether such action by FDA could

precipitate a drug shortage or exacerbate an existing drug shortage. If FDA notifies Defendants in writing that a drug is to be deleted from this list, Defendants shall immediately cease manufacturing and distributing the drug(s), except that Defendants may: (a) complete any manufacturing in progress as of the date of the notice; (b) for sixty (60) days, commence manufacturing that was scheduled before the date of the notice; and (c) distribute finished drug product that was in inventory and/or was manufactured in accordance with this paragraph.

MANAGEMENT CONTROLS

12. Defendants shall select and retain an independent person or persons (the "management controls expert") to prepare a detailed written report on management controls at the BVL facilities as described below. The management controls expert shall be qualified by background, training, education, and experience and shall be without personal or financial ties -- other than a consulting agreement with BVL -- to Defendants or their immediate families and may, if Defendants choose, be the same person(s) retained as the expert pursuant to paragraph 6.A. Defendants shall notify FDA in writing as to the identity and qualifications of this management controls expert within ten (10) days of retaining such expert. This report shall be delivered to BVL's President/CEO within ninety (90) days after the entry of this Decree, and shall, at a minimum:

A. Describe BVL's current organizational structure and the specific roles and responsibilities of each department involved in manufacturing of drugs at the BVL facilities;

B. Assess the role and personnel resources of BVL's QA/QC units, including the units' current role in detecting and correcting all deficiencies and noncompliance with BVL's SOPs at the BVL facilities; and

C. Evaluate whether personnel responsible for directing and conducting the manufacture and quality control of drugs at and/or from the BVL facilities are adequate in number and qualifications (education, training, and experience, or a combination thereof) to ensure compliance with the Act, its implementing regulations, and this Decree.

13. The President of BVL shall, within one hundred and fifty-five (155) days after receipt of the management controls expert's report under paragraph 12, submit to FDA a copy of the report together with a description of any and all actions Defendants propose to take in response to the report and a timetable for completing those actions. This proposal and timetable are subject to approval by FDA.

YEARLY INSPECTIONS BY THE AUDITOR

14. In accordance with the schedule set forth in subparagraph A below, Defendants shall retain an independent person or persons ("the auditor") to conduct audit inspections

of the BVL facilities' manufacturing and quality operations. The auditor shall be qualified by background, training, education, and experience to conduct such inspections and shall be without personal or financial ties -- other than the consulting agreement with BVL -- to Defendants or their immediate families and may, if Defendants choose, be the same person(s) retained as the expert pursuant to paragraphs 6.A. and/or 12. Defendants shall notify FDA in writing as to the identity and qualifications of the auditor within ten (10) days of retaining the auditor.

A. The audit inspections required in this paragraph shall begin within one (1) year after issuance of the notification described in paragraph 6.H, and shall thereafter be conducted annually for an additional three (3) years, for a total of four (4) inspections.

B. At the conclusion of each audit inspection, the auditor shall prepare a detailed audit report (the "audit report") outlining the auditor's findings and analyzing whether Defendants are in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom (the "audit report observations"). As part of each audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations.

The auditor shall deliver each report contemporaneously to Defendants and FDA no later than twenty (20) days after the date the inspection is completed.

C. If an audit report contains information indicating that Defendants are not in compliance with the Act, its implementing regulations, and this Decree, Defendants shall correct those audit report observations within thirty (30) days after receiving the audit report, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, within fifteen (15) days after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) days, Defendants shall submit to FDA in writing a proposed schedule and plan for completing the corrections ("correction schedule") and provide justification describing why the additional time is necessary. The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. Within sixty (60) days after receipt of the correction schedule, FDA will either approve the schedule or, if it is not approved, so notify Defendants and provide the reason(s) for non-approval and specify steps to be taken by Defendants in order to secure FDA approval. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule.

D. Within thirty (30) days after Defendants receive an audit report, unless FDA has notified Defendants in writing that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct any audit report observations. Within twenty (20) days after the auditor concludes that review, the auditor shall report, in writing, whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected. The auditor shall submit this report contemporaneously to Defendants and FDA.

GENERAL PROVISIONS

15. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the expert, the auditor, or any other information that Defendants have failed to comply with the Act, its implementing regulations and/or this Decree, or that additional corrective actions are necessary to achieve such compliance, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions with respect to the BVL facilities and/or with respect to drugs manufactured, processed, packed, labeled, held and/or distributed at and/or from the BVL

facilities, including but not limited to, ordering Defendants to immediately take one or more of the following:

A. Cease all manufacturing, processing, packing, labeling, holding, and/or distributing any or all drugs;

B. Recall, at BVL's expense, drugs in accordance with procedures identified by FDA;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA; and/or

E. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants' drugs and facilities into compliance with the Act, its implementing regulations, and this Decree.

16. The following process and procedures shall apply when FDA issues an order under paragraph 15, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, within ten (10) days after receiving such an order, Defendants shall notify FDA in writing either that:

1. Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or

2. Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable) and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court stays, reverses, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 25 of this Decree.

D. The process and procedures set forth above in paragraphs 16(A)-(C) shall not apply to any order issued

pursuant to paragraph 15 if such an order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition the Court for relief while they implement the order.

17. Any cessation of operations or other action described in paragraph 15 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree, and that Defendants may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA will determine within sixty (60) days after receipt of the request whether Defendants appear to be in such compliance and if so, issue to Defendants a written notification permitting resumption of operations. The costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 15 shall be borne by BVL at the rates specified in paragraph 21 of this Decree.

18. Upon receipt of FDA's final notification for all BVL facilities issued under paragraph 6.H, Defendants and each and all of their directors, officers, agents, employees,

representatives, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, shall be permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly causing to be introduced and/or delivered into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and/or from causing the adulteration of any drug while such drug is held for sale after shipment of one or more of its components in interstate commerce. If, and for so long as, an individual Defendant or an employee of BVL ceases to be employed by or act on behalf of BVL, then that Defendant or employee shall not be subject to the terms of this Decree except as to such individual's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or act on behalf of BVL.

19. Subparagraphs A-C below shall be applicable to FDA's review and/or approval of NDAs, ANDAs, and supplements submitted by BVL and pending FDA review as of the entry of this Decree and NDAs, ANDAs, and supplements submitted by BVL after entry of this Decree:

A. If, after FDA issues a notification for a specific facility or facilities, line(s), or system(s) pursuant to paragraph 7.C, BVL submits an NDA, an ANDA, or a supplement

to an approved application for a drug (not on Attachment A) that is to be manufactured in that facility or facilities, line(s) or system(s), FDA will review and consider the application or supplement in the ordinary course of business (including conducting the scientific review and any necessary pre-approval inspection ("PAI")), and may make an approval determination with regard to that application or supplement.

B. If BVL has pending or submits an NDA, an ANDA, or a supplement to an approved application for a drug (not on Attachment A) to be manufactured in a facility or facilities, line(s) or system(s) for which FDA has not issued a notification pursuant to paragraph 7.C, FDA will conduct its scientific review of the application or supplement in the ordinary course of business, up to the point of making an approval determination, notwithstanding that any necessary PAI may not take place until FDA has issued a notification pursuant to paragraphs 6.G or 7.C for the BVL facility, line, or system referenced in that application or supplement.

C. If BVL has pending or should submit a supplement to an application for a drug listed on Attachment A, FDA will conduct its scientific review of the supplement in the ordinary course of business, may conduct a PAI, and may, if in FDA's discretion it deems appropriate, permit the manufacture and distribution of the drug that is the subject of the supplement.

:

20. All communications required to be sent to FDA under this Decree shall be prominently marked "Decree Correspondence" and, unless otherwise specified herein, sent to the District Director, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237. All communications required to be sent to Defendants under this Decree shall be marked "Decree Correspondence" and shall be sent to Ben Venue Laboratories, Inc., 300 Northfield Road, Bedford, Ohio 44146 to the attention of the Office of Executive Division Counsel, Legal Department and addressed separately to each of the individual defendants.

21. BVL shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $.555 per mile for travel expenses by automobile, government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In

the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

22. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the BVL facilities and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to the BVL facilities, including, but not limited to, all buildings, equipment, drugs, containers and packaging materials therein, labeling, and other promotional material therein; to take photographs and make video recordings; to collect samples (without charge to FDA) of any drugs, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, receiving, holding, and distribution of any and all drugs. The costs of all such inspections, record reviews, and sample analyses shall be borne by BVL at the rates specified above in paragraph 21. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority described in this paragraph shall be separate and

apart from, and in addition to, statutory authority granted to FDA to make inspections under the Act, 21 U.S.C. § 374.

23. A. Within fifteen (15) days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service, delivery via electronic mail with acknowledgement of receipt, or certified mail (return receipt requested), to each and all of the following "Associated Persons": (i) BVL's directors, officers, agents, representatives, attorneys, and to those BVL employees, employees of the expert and the management controls expert working at BVL, and all other persons who are at the BVL facilities and in active concert or participation with Defendants' manufacture, processing, packing, storage, and/or distribution of drugs at the BVL facilities; and (ii) all parties for whom BVL contract manufactures drugs. For purposes of the "other persons" described in the preceding sentence, providing a copy of this Decree to the CEO or most responsible person at the entity shall constitute providing a copy of the Decree to any person employed by that entity. In the event that, at any time after entry of this Decree, BVL becomes associated with any new Associated Person(s), Defendants shall: (i) within ten (10) days of such association, provide a copy of this Decree to such person(s) by personal service, delivery via electronic mail with acknowledgement of receipt, or certified

mail (return receipt requested); and (ii) on a quarterly basis, notify FDA in writing when and to whom the Decree was provided. Within ten (10) days after the entry of this Decree, Defendants shall prominently post a copy of this Decree in all employee common areas in the BVL facilities so that it is accessible to all employees. Defendants shall ensure that the Decree remains posted in the employee common areas as long as it is in effect.

B. Within thirty (30) days after the entry of this Decree, Defendants shall provide FDA an affidavit stating the fact and manner of compliance with this paragraph and identifying the names and positions of all persons receiving copies of the Decree pursuant to the first sentence of subparagraph A above. Thereafter, within ten (10) days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

24. A. Defendants shall notify FDA in writing at least fifteen (15) days before any of the following events occur if the event may affect Defendants' obligations arising out of this Decree: any corporate reorganization, relocation, dissolution, bankruptcy, assignment or sale resulting in the emergence of a successor, the creation or dissolution of subsidiaries, or any other change in BVL's corporate structure or legal status.

B. Defendants shall serve a copy of this Decree on any prospective purchaser or assignee at least fifteen (15) days prior to such an assignment or change in ownership. Defendants shall furnish FDA with an affidavit of compliance with this paragraph sworn to by counsel for Defendants no later than ten (10) days prior to such assignment or change in ownership.

25. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

26. Defendants may at any time petition FDA in writing to extend any time frame or revise any schedule provided herein, and FDA may, in the exercise of its discretion, grant such an extension without seeking leave of court. Any such petitions shall not become effective or stay the impositions of any payments under this Decree unless granted by FDA in writing.

27. If Defendants fail to comply with any provision of this Decree, including any time frame imposed by this Decree, BVL shall pay to the United States Treasury as liquidated

damages the sum of twenty thousand dollars ($20,000) per violation of this Decree and an additional sum of twenty thousand dollars ($20,000) for each day such violation continues. The failure, as determined by the expert or FDA, to satisfactorily correct any audit report observations in accordance with the timeframes approved by FDA shall constitute a "violation" for the purposes of this paragraph. Further, the failure, as determined by either the expert or FDA, to satisfactorily complete one or more numbered steps in the remediation plan or the plan referred to in paragraph 6.G.2 and incorporated by reference in paragraph 7.B. in accordance with the timeframes approved by FDA shall constitute a "violation" for purposes of this paragraph. The amount of liquidated damages imposed under this paragraph shall not exceed twenty million dollars ($20,000,000) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

28. Defendants shall notify FDA of any temporary or permanent discontinuance in the manufacture and/or distribution of any drug listed on Attachment A in accordance with the Act and applicable requirements.

29. This Decree resolves only those claims set forth in the Complaint in this action, and does not affect any civil,

criminal, or administrative claims that the government may now have or bring in the future against the Defendants herein.

30. The parties acknowledge that the payment(s) under this Decree are not a fine, penalty, forfeiture, or payment in lieu thereof.

31. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained at the BVL facilities a state of continuous compliance with laws and regulations, the Act, and this Decree for the preceding sixty (60) months, Plaintiff will not oppose such petition.

32. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, BVL shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to contempt proceedings.

33. If Defendants notify FDA in writing twenty (20) days prior to Defendants' cessation of any manufacturing, processing, packing, holding and/or distributing of any drug at and/or from the BVL facilities as of a specific date, then Defendants' obligations related to paragraphs 6 and 14 as to those actions shall also cease as of that date.

34. This Court shall retain jurisdiction over this action

and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

Dated this 31st day of January, 2012.

UNITED STATES DISTRICT JUDGE

and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

Dated this 31st day of January, 2013.

UNITED STATES DISTRICT JUDGE

Entry Consented to:
For Defendants

GEORGE P. DOYLE III
Individually and on behalf of
Ben Venue Laboratories, Inc. as
President and Chief Executive
Officer

KIMBERLY A. KELLERMANN
Individually

DOUGLAS A. RICH
Individually

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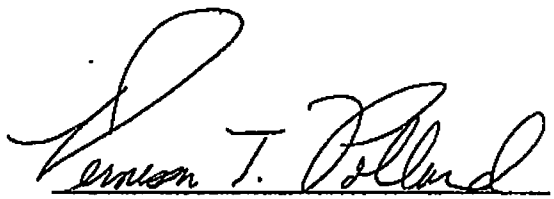

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(202) 942-5811
Counsel for Kimberly A.
Kellermann

Attachment A

PRODUCT

1. ACETAZOLAMIDE
2. ACETYLCYSTEINE
3. ACTHREL
4. ACYCLOVIR SODIUM
5. ADENOSINE
6. ALLOPURINOL SODIUM
7. ALPROSTADIL
8. AMIKACIN
9. AMPHOCIL (AMPHOTERICIN B)
10. ATRACURIUM BESYLATE
11. AZATHIOPRINE
12. AZTREONAM (CAYSTON)
13. BiCNU
14. BLEOMYCIN
15. BUMETANIDE
16. BUPRENORPHINE
17. BUSULFEX (BUSULFAN)
18. BUTORPHANOL
19. CAFCIT (CAFFEINE CITRATE)
20. CARBOPLATIN
21. CARDIOLITE (SESTAMIBI)
22. CEPLENE (HISTAMINE DIHYRDOCHLORIDE)
23. CHLOROPROCAINE
24. CISPLATIN
25. CLADRIBINE
26. CLINDAMYCIN
27. CYCLOSPORINE
28. CYTARABINE
29. DACARBAZINE
30. DACTINOMYCIN
31. DAUNORUBICIN
32. DEFEROXAMINE MESYLATE
33. DEFINITY (PERFLUTREN)
34. DEXRAZOXANE
35. DICYCLOMINE HCL
36. DIHYDROERGOTAMINE
37. DILTIAZEM HCL
38. DIPYRIDAMOLE
39. DOBUTAMINE HCL

40. DOXAPRAM HCL
41. DOXIL
42. DOXORUBICIN/ADRIAMYCIN
43. DOXYCYCLINE
44. ELUANT (SODIUM CHLORIDE)
45. ENALAPRILAT
46. ESMOLOL HCL
47. ETHYOL (AMIFOSTINE)
48. ETOMIDATE
49. ETOPOSIDE
50. FAMOTIDINE
51. FLOXURIDINE
52. FLUCONAZOLE
53. FLUDARA
54. FLUMAZENIL
55. FLUPHENAZINE DECANOATE
56. GANCICLOVIR
57. HALOPERIDOL DECANOATE
58. HALOPERIDOL LACTATE
59. HEXVIX
60. IDARUBICIN HCL
61. IFOSFAMIDE
62. IMMITICIDE
63. INAMRINONE
64. INDOMETHACIN
65. IRINOTECAN HCL
66. KETAMINE HCL
67. KETOROLAC
68. LABETALOL HCL
69. LEUCOVORIN CALCIUM
70. LEVOCARNITINE
71. LEVOTHYROXINE SODIUM
72. LYMPHAZURIN
73. MELPHALAN
74. MESNA
75. METHOTREXATE
76. METOPROLOL TARTRATE
77. MIDAZOLAM
78. MILRINONE LACTATE
79. MITOMYCIN
80. MITOXANTRONE
81. NEOPROFEN (IBUPROFEN LYSINE)
82. NEUROLITE AND NEUROLITE BUFFER

83. NOREPINEPHRINE
84. OCTREOTIDE
85. ONDANSETRON
86. ORPHENADRINE
87. PACLITAXEL
88. PAMIDRONATE DISODIUM
89. PENTOSTATIN
90. PHENTOLAMINE MESYLATE
91. POLYMYXIN B
92. PROCHLORPERAZINE
93. PROPOFOL
94. PROPRANOLOL HCL
95. RANITIDINE
96. RIFAMPIN
97. ROMIDEPSIN
98. TERBUTALINE SULFATE
99. TESTOSTERONE CYPIONATE
100. THIOTEPA
101. VALPROATE SODIUM
102. VECURONIUM BROMIDE
103. VINBLASTINE SULFATE
104. VINORELBINE USP
105. VIRAZOLE
106. NATIONAL CANCER INSTITUTE PRODUCTS